REMARKS

I. Status of the Application

Claims 1-17 are presently pending in the application. Claims 1-17 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Claims 1-4 and 6-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Freeman, U.S. Patent No. 3,919,773 (hereinafter "Freeman"). Claims 5 and 9-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Freeman in view of Polson et al., U.S. Patent No. 5,487,897 (hereinafter "Polson"). Applicants respectfully request reconsideration of the pending claims in view of the following amendments and remarks.

Applicants have amended the claims to more clearly define and distinctly characterize Applicants' novel invention. Specifically, independent claims 1 and 2 have been re-worded to recite "a rigid biodegradable polymer or copolymer matrix" instead of "a rigid matrix component containing at least one biodegradable polymer or copolymer." Support for this amendment can be found throughout the specification as filed, for example in paragraphs [0020], [0025], and the Examples. Claims 1 and 2 have been amended to clarify that the claims are in product form, the product having the recited properties. Claims 1, 2, 9, and 10 have been amended to recite a plasticizer-created porous surface. Support for these amendments can be found throughout the specification as filed, for example, at paragraph [0025]. Lines 20-21 of paragraph [0025] disclose, "Pores are created on the surface of the implant of the invention when NMP dissolves or evaporates from the implant." Claims 1, 2, 9 and 10 have been amended to more clearly define a property of the implant: the plasticizer is operative to substantially exit from the implant after coming into contact with tissue fluids of the organ system. Claims 1, 2, 9 and 10 have also been amended to correct formal matters. Claim 10 has been amended to clarify that the

plasticizer is added after the biodegradable polymer or copolymer has been formed into the matrix of an implant. Support for this amendment can be found throughout the specification as filed, for example in Example 1. Claim 5 has been amended to place it in proper Markush group format. Claims 11-15 and 17 have been amended to depend from claim 10 instead of claim 9. Support for this amendment can be found throughout the application as filed.

The amendments presented herein add no new matter. Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration of the application in view of the following remarks, which are intended to place this case in condition for allowance.

II. Interview Summary

Applicants are grateful to the Examiner for extending the courtesy of a telephone interview with Applicants' representative on May 22, 2007. Applicants thank the Examiner for a helpful discussion on the new matter rejection of the recited "substantially nonporous core," the novelty rejection over Freeman, and the Examiner's opinion that the claims are in product-by-process form. The amendments and remarks presented in this paper are intended to address the Examiner's concerns.

III. Claims 1-17 Do Not Recite New Matter

At page 2 of the final Office Action issued on September 22, 2006, claims 1-17 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. The Examiner is of the opinion that there is no teaching or reasonable suggestions in the originally filed disclosure that demonstrate the core being "substantially nonporous." The Examiner states that, although the surface is disclosed, the specification remains silent as to the

core of the device. The Examiner concludes that the evidence pointed out by Applicants does not constitute the original disclosure, and, therefore, any amendments based on those later additions constitute new matter. Applicants respectfully traverse this rejection.

The first paragraph of 35 U.S.C. § 112 requires that the specification provide a written description of the claimed invention:

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The purpose of the written description requirement is to ensure that the specification conveys to those skilled in the art that the applicants possessed the claimed subject matter as of the filing date sought. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). Applicants submit that the claimed invention is described with sufficient particularity to demonstrate that Applicants had possession of the claimed invention, namely, a biodegradable implant having a plasticizer-created porous surface and a substantially nonporous core.

Applicants' originally filed specification includes a description of how to make the claimed implants, and following Applicants' teachings provided in the original specification results in the production of an implant having a plasticizer-created porous surface and a substantially nonporous core. Please see the concurrently filed declaration of co-inventor Eija Pirhonen, stating that she made an embodiment of the claimed implant according to the method taught in Example 1 of the specification as filed, and the end result was an implant having porous surfaces and a substantially non-porous core, as evidenced by the scanning electron microscope (SEM) image of a cross-section of the implant (see Attachment A of this paper, which was

originally submitted at Tab C of Applicants' Amendment and Response filed December 15, 2005). In addition to Example 1, Applicants' originally filed specification provides the following teachings: at Example 3, Applicants teach how to immerse a compression molded PLLA/PGA/TMC copolymer sample in plasticizer for 30 seconds, followed by a 20 minute diffusion step to allow the plasticizer to diffuse into the copolymer; at Example 4, Applicants provide a protocol for compression pressing a variety of polymer granulates, making polymer strips and immersing polymer strips in a plasticizer for 40 seconds, followed by a 30 minute incubation in a metal net to ensure diffusion of plasticizer into the polymer. Each of these methods produces the claimed implant having a plasticizer-created porous surface (see also Figure 3 and paragraph [0025] of the specification).

Although the instant specification does not expressly state the physical characteristics of the core, the protocols provided by Applicants ***necessarily*** result in the formation of an implant having a substantially nonporous core, as attested to by the attached inventor declaration. Because it is the exit of the plasticizer (e.g. by evaporation or diffusion or dissolution) from the claimed implant that causes pore formation, and because Applicants' specification teaches soaking the implant for only 30 or 40 seconds, one of skill in the art of implants would instantly appreciate that the plasticizer would only be present in the implant at the surface, and that this is implicit in Applicants' disclosure. The minimal contact time of the implant with the plasticizer simply would not be sufficient for allowing the plasticizer to diffuse beyond the surface of the implant. In fact, Applicants teach "when the plasticizer diffuses from the implant, a ***porous layer is formed on the outer surfaces*** of the implant" (paragraph [0017], emphasis added). Thus, one of skill in the art would recognize that the instant specification provides adequate written description of an implant having a plasticizer-created porous surface and a substantially

nonporous core. Simply because Applicants' specification does not *ipsis verbis* state that the claimed implants have a substantially nonporous core does not mean that recitation of this claim limitation represents new matter. It is well settled case law that one need not include the exact claim language into the specification to meet the written description requirement. Indeed, the nonporous core is an ***inherent*** physical characteristic and a necessary result of implants made by one of skill in the art guided by the teachings of Applicants' specification.

For at least the foregoing reasons, Applicants respectfully request that the rejection of claims 1-17 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement be reconsidered and withdrawn.

IV. Claims 1-4 and 6-8 Are Novel over Freeman

At page 3 of the final Office Action issued on September 22, 2006, claims 1-4 and 6-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Freeman. The Examiner is of the opinion that the implant matrix of Freeman comprises a mixture of biocompatible polymers along with other biodegradable polymers. The Examiner states that upon implantation the biodegradable polymer dissolves with contact with bodily fluids, leaving a porous surface and a solid (non-porous) core. The Examiner is further of the opinion that claim limitations drawn to plasticizer are process limitations in product-by-process claims, and thus are not given patentable weight. Applicants respectfully traverse this rejection.

Applicants' claimed invention is directed in part to a ***biodegradable implant*** that is ***flexible*** and ***rigid*** prior to insertion into an organ system, wherein the bending resistance of the implant prior to insertion of the implant into the organ system is substantially lower than after its insertion. The biodegradable implant comprises a rigid ***biodegradable*** polymer or copolymer

matrix and a plasticizer dispersed within the rigid matrix, wherein the plasticizer is operative to substantially exit from the implant after coming into contact with tissue fluids, and wherein the implant has a ***plasticizer-created*** porous surface and a substantially non-porous core.

Freeman fails to disclose, teach or suggest each and every limitation of Applicants' claimed invention. Specifically, Freeman fails to disclose a biodegradable implant comprising a rigid ***biodegradable*** polymer or copolymer ***matrix***. In contrast, Freeman discloses implant material that is moldable, polymerizable, and biologically compatible (col. 3, lines 30-35, col. 4, lines 1-3). This biologically compatible material makes up the body, or matrix, of the implant. Freeman then distinguishes the moldable, polymerizable, biologically compatible material that makes up the matrix of the implant from a particulate (e.g. polylactic acid or polyglycolic acid) which coats the matrix. Col. 4, lines 4-8 of Freeman teaches, "Once the material has been prepared and while the material is still moldable, it is rolled in, dusted, or otherwise coated with a particulate so that the particulate becomes embedded in the outer surface of the [moldable, polymerizable, biologically compatible] material." Indeed, Webster's Ninth New Collegiate Dictionary defines "matrix" as a "material in which something is enclosed or embedded." Thus, the particulate embedded as a coating on the outer surface of the matrix material is ***not*** part of the matrix material. Although the matrix material of Freeman's implant is ***biologically compatible***, nowhere does Freeman teach or suggest the desirability of using an implant made of a ***biodegradable*** matrix material. In fact, Freeman provides many examples of the long-term stability of its implants after implantation. For example, Freeman teaches that its implants "form the basis for a crown or other suitable dental restoration" (column 3, lines 10-11); that the implant "maintains the normal oral geometry intact during the healing period" and that the "exposed implant material may then be removed or shaped to receive a crown or other suitable

restoration *at some later date*" (column 4, lines 49-52, emphasis added); and that their implants may be used "to replace missing bone" (column 7, lines 7-9). Thus, the implants of Freeman are not biodegradable, that is, Freeman's implants will not dissolve in an organ system, but form a permanent structural support unless surgically removed. In contrast, Applicants' biodegradable implant comprises a biodegradable polymer or copolymer matrix, so that the whole body of the implant is capable of dissolving in an organ system (see specification page 2, lines 28-31). Therefore, the physical properties of Applicants' claimed implants differ markedly from the physical properties of the implants taught by Freeman.

In addition, Freeman is directed to an implant made of a moldable, non-biodegradable matrix, not a biodegradable implant that is ***flexible*** and ***rigid*** prior to insertion into an organ system. The moldable matrix of Freeman is easily shapeable. Freeman teaches, "[s]ince the material is moldable, it easily fills and conforms to the shape of a tooth socket" (column 4, lines 25-26). Thus, the implants of Freeman do not possess the physical property of being flexible and rigid ***prior to insertion into an organ system***. In contrast, Applicants' claimed implant maintains sufficient rigidity prior to insertion to provide structural integrity, as well as the flexibility to enable it to be shaped to fit a tissue structure in a very precise manner such that a good fit may be achieved upon implantation.

Applicants have amended the subject claims to recite a biodegradable implant having a plasticizer-created porous surface and a substantially nonporous core. The Examiner is of the opinion that Freeman also discloses an implant with a porous surface and a solid (nonporous) core. However, the porous surface of Freeman's implant is structurally distinct from the ***plasticizer-created*** porous surface of the claimed invention. The porous surface of Freeman's implant is not created by liquid plasticizer exiting the implant, but instead is created by the

dissolution of particulate material that has been embedded in the surface of the implant. The particulates create pores that mimic their shape, that is, pores that are generally spherical or round, having convex walls. In contrast, the plasticizer creates pores that are irregularly shaped, often having concave walls (see Attachment A). Thus, Freeman fails to disclose, teach or suggest an implant having a plasticizer-created porous surface.

The Examiner is of the opinion that the claim limitations drawn to a plasticizer do not impart patentability to the claims because they are process limitations in a product-by-process claim format. Applicants respectfully disagree in view of the amended claims. The subject independent claims have been amended to clarify that the claimed biodegradable implant comprises a rigid biodegradable polymer or copolymer matrix and a plasticizer dispersed within the rigid matrix. The biodegradable implant possesses the recited physical characteristics, such as being flexible and rigid prior to insertion into an organ system, comprising plasticizer which is operative to substantially exit from the implant after coming into contact with tissue fluids of an organ system, having a substantially lower bending resistance prior to insertion into an organ system than after insertion, having a plasticizer-created porous surface and a substantially nonporous core. Thus, the subject claims are in product format, not product-by-process format. Since these product claims positively recite plasticizer as a claim limitation, the presence of plasticizer in Applicants' biodegradable implant cannot be excluded from consideration for patentability. Freeman fails to disclose, teach or suggest the inclusion of a plasticizer in its implant, much less the inclusion of N-methyl-2-pyrrolidone (NMP).

For at least the foregoing reasons, the Freeman reference fails to teach or suggest each and every element of Applicants' claimed invention. Accordingly, Applicants request that the rejections of claims 1-4 and 6-8 under 35 U.S.C. §102(b) be reconsidered and withdrawn.

V. Claims 5 and 9-17 Are Non-Obvious over Freeman in View of Polson

At page 4 of the final Office Action issued on September 22, 2006, claims 5 and 9-17 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Freeman in view of Polson. The Examiner admits that Freeman is silent to the inclusion of active agents that aid in implantation and bone/tissue growth. The Examiner states that it would have been obvious to include the solvents of Polson into the implant of Freeman in order to provide a more stable implant formulation, and to improve the solubility of active agents aiding in the healing process. The Examiner concludes that one of ordinary skill in the art would have been motivated to combine the teachings as such with an expected result of properly solubilized implant capable of improving the healing process. Applicants respectfully traverse this rejection.

The combination of Freeman and Polson fails to teach or suggest each and every limitation of the claimed invention. Specifically, Polson fails to teach or suggest the steps of ***first*** forming the implant from the biodegradable polymer or copolymer matrix component, and ***then*** adding a plasticizer to the formed matrix component. Instead, Polson teaches that a liquid polymer solution is formed into an implant precursor, that is, an organic solvent such as NMP is always added to the polymer ***before*** being formed into an implant (col. 3, lines 12-22).

Polson fails to teach or suggest the claimed implant or methods of making the claimed implant. Polson is directed to an implant comprising an outer sac with a ***liquid component*** contained within (column 2, lines 14-15). Such an arrangement would not create a ***rigid*** implant, as required by the instant claims, much less an implant that has the property of being both flexible and rigid prior to insertion into an organ system. In fact, Polson. teaches that, "***[u]nlike a solid implant***, the implant precursor is easy to manipulate and may be shaped and molded

within the defect site as it solidifies. Advantageously, the moldability of the implant precursor allows it to conform to irregularities, crevices, cracks, holes, and the like, in the tissue defect site" (column 5, lines 2-7, emphasis added). Thus, both Freeman and Polson. fail to teach or suggest a rigid implant, as claimed by Applicants.

Polson also fails to disclose implants or methods to manufacture implants having a nonporous core, as required by the claimed implants. Instead, Polson teaches a solid implant having a microporous matrix (column 2, lines 9-10). Thus, the core of Polson contains pores. For at least these reasons, Polson fails to teach or suggest the claimed invention.

In addition, one of skill in the art would not be motivated to combine the teachings of Freeman and Polson to arrive at the claimed invention. Substituting a biodegradable polymer for the biologically compatible but non-biodegradable matrix of Freeman renders the implant of Freeman unsuitable for its intended use as permanent structural support. Also, the liquid polymer solution of Polson's implant matrix, comprising a biodegradable polymer dissolved in NMP, produces a highly porous inner core and a comparatively less porous outer surface layer (col. 2, lines 37-41). The skilled artisan wishing to produce an implant having a porous surface and a substantially nonporous core would not be motivated to include NMP in the matrix material of Freeman, because including NMP in the matrix material is taught by Polson to produce a highly porous core.

Furthermore, Freeman and Polson cannot be combined to arrive at the claimed invention with a reasonable expectation of success. The combination of Freeman and Polson would result in the formation of a material that would be ***unsuitable for use as an implant.*** Although the Examiner asserts that it would have been obvious to include the solvents of Polson into the materials of Freeman in order to provide a more stable implant formulation, this is not so.

Freeman teaches that its implants are cured by polymerization *in situ* (column 2, lines 23-25). Thus, their implants are cured after implantation in the body. Adding a solvent such as NMP to the matrix material of Freeman prior to curing/polymerization (i.e., prior to implantation) would interfere with the ability of the implant to properly cure. Specifically, the NMP of Polson. would dissolve and/or wash away monomeric components present in the implant material of Freeman prior to polymerization, thus preventing at least some of the monomers from participating in polymerization. This would cause the implant material to be unstable because it has not completely hardened, and would render it unsuitable for use as an implant. Accordingly, such an implant would not be appropriate to use as an anchor for a dental implant or to replace bone, which Freeman teaches are desired functions for their implants. Therefore, the combination of these references fails to produce a stable implant, let alone Applicants' claimed implant.

For at least these reasons, the combination of Freeman and Polson fails to render the claimed invention obvious. Accordingly, Applicants request that the rejections of claims 5 and 9-17 under 35 U.S.C. §103(a) as being unpatentable over Freeman in view of Polson be reconsidered and withdrawn.

VI. CONCLUSION

Having addressed all outstanding issues, Applicants respectfully request entry and consideration of the foregoing amendments and reconsideration and allowance of the case. To the extent the Examiner believes that it would facilitate allowance of the case, the Examiner is requested to telephone the undersigned at the number below.

Respectfully submitted,

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